DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Mycamine - NDA 21-754
Docket No.: 2006E-0023
2006E-0345

SEP 11 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Patent Extension
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for U.S. Patent No. 6,107,458 and 6,265,536, filed by Astellas Pharma, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for Mycamine (micafungin sodium), the human drug product claimed by the patents.

The total length of the regulatory review period for Mycamine (micafungin sodium) is 2,546 days. Of this time, 2,221 days occurred during the testing phase and 325 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: March 29, 1998.

   The applicant claims June 30, 2003, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 29, 1998, which was thirty days after FDA receipt of the original IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: April 26, 2004.

   The applicant claims April 23, 2004, as the date the new drug application (NDA) for Mycamine (micafungin sodium) (NDA 21-754) was initially submitted. However, FDA records indicate that NDA 21-754 was submitted on April 26, 2004.

3. The date the application was approved: March 16, 2005.

FDA has verified the applicant's claims that NDA 21-754 was approved on March 16, 2005.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Stephen G. Baxter
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